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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,806	05/08/2006	Deepak Gandhi	077567-0018	6159

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ART UNIT	**PAPER NUMBER**
3738	

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11/10/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,806	GANDHI ET AL.	
	Examiner	Art Unit	
	JASON-DENNIS STEWART	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,9-14,17,18 and 40-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 9-14, 17, 18, and 40-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The following is a Final Office action in response to communications received on 09/14/2010. Claims 1, 2, 40, and 41 have been amended. Claims 4-8, 15, 16, and 19-39 have been cancelled. Claims 51-58 have been added. Therefore, Claims 1-3, 9-14, 17, 18, and 40-58 are currently pending and addressed below.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 51,54,55 and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 51 and 55 are indefinite. It is unclear what “material” is being referenced. Claim 1 sets forth an alloy comprising three materials.

2. With respect to claims 54 and 56, it is unclear what the Applicant means by "thickness" of the stent. It is unknown whether this term is referring to diameter, wall thickness, or something else. This renders the claim indefinite; however, the claim was examined as best understood.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-3, 10, 12-14, 17, 18, 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sahota 2003/0181973 in view of Brazzle et al. (" A Hysteresis-free platinum alloy flexure material for improved performance and reliability of MEMS devices").

5. Sahota teaches a stent and a delivery system that may be used in the brain (paragraph 41). The stent may be self-expandable or balloon expandable (paragraph 19) (Claims 3, 17). The stent may be cut from a flat sheet or a tube of material (paragraph 72). Sahota also teaches that the stent may have end markers to enhance visibility (Fig. 7a). Sahota further teaches the use of therapeutic coatings on the stent for drug delivery (paragraph 14) (Claim 12).

Sahota teaches the invention as claimed and as discussed above. However, Sahota does not disclose the use of an alloy made of about 75-80% platinum, 12-18% of rhodium, and 5-10% or ruthenium.

Brazzle teaches the use of Alloy 851 (a trade name for a platinum alloy having 79% platinum, 15% rhodium, and 6% ruthenium) in MEMS (microelectromechanical systems) as an ideal spring material.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent of Sahota with the alloy taught by Brazzle in order to gain desirable properties such as biocompatibility and extreme corrosion resistance as taught by Brazzle (abstract). It should be noted that limitations regarding the flexibility of the stent Since the composition of the alloy 851 as taught by Brazzle is within in range as claimed, examiner maintains that the physical properties (i.e. flexibility) of the two alloys would be essentially similar, if not, the same. Applicant's specification, page 12, admits that no special techniques are required in the fabrication of the stent. Therefor absent any further claimed structural differences, the stent of Sahota as modified by Brazzle would possess similar, if not the same, physical properties.

Regarding claim 51, in so far as definite, examiner is interpreting the ratio to be met by the stent of Sahota as modified by Brazzle.

Regarding Claims 52-53, applicant's specification has failed to set forth criticality and/or unexpected results directed to the various physical properties as claimed. It has been held that "the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." *In re Petersen.* **See MPEP 2144.05, Section II, Part A.**

6. Claims 9 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sahota 2003/0181973 in view of Brazzle et al. (" A Hysteresis-free platinum alloy flexure material for improved performance and reliability of MEMS devices"), as applied to Claim 1 above, and further in view of Alt 6,767,360 or Brenneman 5,957,929.

7. Sahota in view of Brazzle teaches the invention as claimed and as discussed above. However, Sahota does not explicitly teach a stent having a dimensional sidewall thickness. However, in paragraph [0052], Sahota teaches that the stent thickness will vary dependent on the specified treatment. Alt '360 teaches that a coronary stent has a sidewall thickness of 100 microns or less (col. 7, ll. 50-55). . Note, Brenneman 5957929 teaches intracranial stents having a thickness within the range as claimed.

It would have been obvious to one of ordinary skill in the art at the time of the invention to form the stent of Sahota with the sidewall width of less than .0028 inches since the particular range is known to be established based upon the desired treatment in the coronary and/or intracranial environment with the stents as taught by Alt (col. 7, ll. 50-55) and/or Brenneman.

8. Claims 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sahota 2003/0181973 in view of Brazzle et al. (" A Hysteresis-free platinum alloy flexure material for improved performance and reliability of MEMS devices"), as applied to Claim 10, further in view Alt 2004/0039438.

9. Sahota in view of Brazzle teaches the invention as claimed and as discussed above. However, Sahota in view of Brazzle does not teach a stent having iridium oxide or titanium nitrate coatings.

Alt '438 teaches a stent having a titanium nitrate or iridium oxide coating as well as therapeutic coatings (abstract) to inhibit tissue irritation and to deliver therapeutics to a local site in the body.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent of Sahota in view of Brazzle with the coatings of Alt '438 in order to prevent tissue irritation and deliver drugs locally in the body.

10. Claims 40-42, 44, 46-50, and 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sahota 2003/0181973 in view of Speidel ("Resistance to fatigue crack growth of the platinum metals").

11. Sahota teaches the invention as claimed and as discussed above. However, Sahota does not teach a stent made of an alloy that has a composition of about 65%-75% of platinum and 25-35% of rhodium.

Speidel teaches that a 70% platinum / 30% rhodium as a useful platinum alloy because rhodium has a higher resistance to fatigue crack growth than most other metals under cyclical stress (abstract).

It would have been obvious to modify the stent of Sahota with the alloy disclosed in Speidel in order to resist fatigue crack growth under cyclical loading as taught by Speidel (abstract) since it is known that stents undergo cyclical stress *in vivo* and manufacturers would be motivated to use alloys that would resist cracking. It should be noted that limitations regarding the flexibility of the stent are interpreted as functional limitations by the Examiner and hold limited patentable weight in the absence of differentiating structure or materials.

Regarding Claims 55-57, it has been held that "the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum

combination of percentages." *In re Petersen.* **See MPEP 2144.05, Section II, Part A.**

12. Claims 43 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sahota 2003/0181973 in view of Speidel ("Resistance to fatigue crack growth of the platinum metals") as applied to Claim 40, further in view of Alt 6,767,360 or Brenneman 5,957,929.

13. Sahota in view of Speidel teaches the invention as claimed and as discussed above. However, Sahota does not explicitly teach a stent having a dimensional sidewall thickness. However, in paragraph [0052], Sahota teaches that the stent thickness will vary dependent on the specified treatment Alt '360 teaches that a coronary stent has a sidewall thickness of 100 microns or less (col. 7, ll. 50-55). . Note, Brenneman 5957929 teaches intracranial stents having a thickness within the range as claimed.

It would have been obvious to one of ordinary skill in the art at the time of the invention to form the stent of Sahota with the sidewall width of less than .0028 inches since the particular range is known to be established based upon the desired treatment in the coronary and/or intracranial environment with the stents as taught by Alt (col. 7, ll. 50-55) and/or Brenneman.

14. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sahota 2003/0181973 in view of Speidel ("Resistance to fatigue crack growth of the platinum metals") as applied to Claim 44, further in view Alt 2004/0039438.

15. Sahota in view of Speidel teaches the invention as claimed and as discussed above. However, Sahota in view of Speidel does not teach a stent having iridium oxide or titanium nitrate coatings.

Alt '438 teaches a stent having a titanium nitrate or iridium oxide coating as well as therapeutic coatings (abstract) to inhibit tissue irritation and to deliver therapeutics to a local site in the body.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent of Mayer in view of Speidel with the coatings of Alt '438 in order to prevent tissue irritation and deliver drugs locally in the body.

Response to Arguments

Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection. It should be noted that the feature of a "stent [that] has a flexibility such that deflection of 1mm from a neutral line occurs with less than 8 grams of force" has been considered to the extent that it further limits the structure of the stent. . Applicant's specification, page 12, admits that no special techniques are required in the fabrication of the stent. Therefore absent any further claimed structural differences, the stent of Sahota as modified by Brazzle would possess similar, if not the same, physical properties. Furthermore, Sahota in view of Brazzle and Sahota in view of Speidel disclose a stent of similar dimensions and materials. These combinations would inherently produce stents of substantially the same flexibility as the stents as claimed.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JASON-DENNIS STEWART whose telephone number is (571)270-3080. The examiner can normally be reached on M-F (alt Fridays off) 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jason-Dennis Stewart/
Examiner, Art Unit 3738

/DAVID ISABELLA/

Supervisory Patent Examiner, Art Unit 3774